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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,686

11/21/2005

Jose Miguel Mulet Salort

BJS-4982-12

4546

23117

7590

02/02/2009

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

02/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,686	<b>Applicant(s)</b> MULET SALORT ET AL.	
	<b>Examiner</b> Cynthia Collins	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 27 and 28 is/are allowed.
- 6) ☒ Claim(s) 29-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### **DETAILED ACTION**

The Amendment filed June 13, 2008, and the reply filed November 7, 2008, have been entered.

Claims 1-26 are cancelled.

Claims 27-39 are new.

Claims 27-39 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-35, and claims 36-39 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claims 34-35 are drawn to a method comprising expressing a protein of claim 27 or claim 28 in yeast. A method comprising expressing a protein of claim 27 or claim 28 in yeast does not find support in the specification as filed, and thus constitutes new matter.

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Claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated protein comprising or consisting of the sequence as given in SEQ ID NO 4, does not reasonably provide enablement for other isolated proteins comprising other amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claim, for the reasons of record set forth for the rejection of claim 18 in the office action mailed February 22, 2008.

Applicant's arguments filed June 13, 2008 have been fully considered but they are not persuasive.

Applicants maintain that the claims are supported by an enabling disclosure, and note that the level of skill in the art of making and screening variant proteins containing a structure of the present claims is advanced. Applicants also point out that the specification teaches alternate means to make and screen proteins of the claims which will be appreciated by those of ordinary skill in the art as not requiring undue experimentation. (reply pages 8-9)

The rejection is maintained because the specification does not provide sufficient guidance with respect to the particular functional attributes of variants of SEQ ID NO:4. Such guidance is necessary because the functional attributes of amino acid sequence variants are unpredictable, since a change of one or more amino acids in a polypeptide can alter or eliminate its function. With regard to making and testing the claimed variant proteins, the Examiner maintains that while the level of skill in the art of making variant proteins containing a structure of the present claims may be advanced, the level of skill in the art of screening variant proteins containing a structure of the present claims is not ascertainable, since the claims require no particular function

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or activity for the variant proteins, and since no particular function or activity for the variant proteins is known in the art or disclosed in the specification. The Examiner also maintains that in view of the unpredictability of the effect of changing amino acids, the level of skill in the art is not sufficient to enable the claimed invention, since the specification provides no guidance with respect to what effect any particular change in the amino acid sequence of SEQ ID NO:4 would have on the function or activity of the resultant variant protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34-35, and claims 36-39 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. Claims 34-35 require expressing a protein of claim 27 or claim 28 in yeast. The proteins of claim 27 or claim 28 are obtained from *Beta vulgaris*, a plant. Accordingly, claims 34 and 35 omit elements that are essential to causing the expression of a plant protein in yeast.

***Allowable Subject Matter***

Claims 27 and 28 are allowed.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Remarks***

Claims 27-39 are deemed free of the prior art, due to the failure of the prior art to teach or suggest an isolated protein comprising or consisting of the sequence of SEQ ID NO:4, or variant proteins comprising a sequence at least 95% identical to SEQ ID NO:4.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cynthia Collins/  
Primary Examiner, Art Unit 1638

CC